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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/007,140	11/05/2001	Lyn Hughes	A01317	1934

21898 7590 05/28/2008

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EXAMINER	
LUDLOW, JAN M	

ART UNIT	PAPER NUMBER
1797	

MAIL DATE	DELIVERY MODE
05/28/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/007,140	HUGHES, LYN	
	Examiner	Art Unit	
	Jan M. Ludlow	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 September 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11/5/2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. Claims 19-25 are objected to because of the following informalities: In claim 19, the last line is redundant with part B). Appropriate correction is required.

2. Claims 19-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 19, it is unclear what metes and bounds are intended by "performing an in vitro buccal dissolution test by" in part f. How does giving the test a different name make the test itself different? The examiner notes that applicant has disclosed that buccal dissolution differs from GI dissolution by having incomplete dissolution, shorter testing times and removing undissolved solids (Background of Invention), but it is not clear which of these is being claimed in that only removing undissolved small particles (indicating incomplete dissolution) is in the claim. In claim 19, it is unclear how the dip-tube of line 2 relates to the "means for transferring" of part B).

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 19-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Compton et al in view of Olson (3,620,675).

Compton teaches a method for sampling a dissolution vessel having a stirrer and temperature control (col. 2, lines 41-48). A sample is withdrawn via needle 20 and particles are removed from the vessel and trapped in filter 32. The needle constitutes the instant dip-tube and the outlet is e.g., at elements 22, 34, 46. Particle-free sample passes through the filter and may be passed to a flow-through analyzer, such as a flow injection analyzer or chromatographic system (col. 4, line 6-12).

Compton fails to explicitly teach passing release medium through the cell or adding a test sample or a UV flow cell.

Olson teaches a dissolution test with a UV flow cell analyzer 23.

It would have been obvious to provide a UV flow cell in the flow through analyzer of Compton in order to analyze dissolution samples as taught by Olson. It would have been obvious to provide release medium and sample in the dissolution vessel in order to test the sample for dissolution as disclosed. Note that the medium "passes through" because it is supplied and withdrawn. With respect to claim 25, it would have been obvious to optimize the size of the needle to remove desired volumes at desired rates. Note further that the instant claims do not preclude back-flushing the particles into the dissolution cell or otherwise distinguish over Compton. In that Compton teaches in vitro dissolution testing in simulated biological fluids (col. 1, lines 16-18) with a rapid

sampling rate (col. 2, line 3) and removal of solids by filtration, it is the examiner's position that Compton teaches "buccal" dissolution, to the extent the term is definite.

4. Applicant's arguments filed September 4, 2007 have been fully considered but they are not persuasive.

Note that "small particle" has been defined in the specification as pointed out by Applicant in the response filed March 17, 2006.

Applicant argues that Compton teaches an apparatus, not a method, but the disclosure includes how the apparatus is to be used, e.g., to pass release medium out of a heated dissolution vessel through a dip leg having an outlet to provide particle-free sample to a measurement cell.

Applicant argues that neither Compton nor Olson teaches or discloses a "buccal" dissolution test, because they do not teach removal of undissolved particles, but Compton does teach removal of undissolved particles via the needle. Olson is relied upon for the type of measuring cell.

5. The following claim amendments drafted by the examiner and considered to distinguish patentably over the art of record in this application, are presented to applicant for consideration:

In claim 19, line 1, change "test," to –test method, said method--.

In claim 19, line 2, change "cell" to –cell, the filtration cell comprising a first chamber separated from a second chamber by a filter, the first chamber--.

In claim 19, line 2, change "also" to –the second chamber--.

In claim 19, line 3, after "outlet" insert –separate from the dip-tube, the outlet being--.

In claim 19, line 4, before "the filtration cell" add --the first chamber of--.

In claim 19, line 8, after "cell" insert –through the outlet--.

In claim 19, line 16, change "test;" to –test.--.

In claim 19, delete the last five lines: "wherein the dissolution test....small particle size."

In claim 25, change "means for transferring the particles out of the cell" to –dip-tube--.

The proposed amendment serves to clarify the differences between the prior art and the instant invention, namely the relative positions of the filter, outlet, uv cell, and dip-tube which permit the particles to be removed form the filtration cell separately from the filtration and UV analysis of the remaining medium.

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jan M. Ludlow whose telephone number is (571) 272-1260. The examiner can normally be reached on Monday, Tuesday and Thursday, 11:30 am - 8:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jan M. Ludlow
Primary Examiner
Art Unit 1797

/Jan M. Ludlow/
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